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ORIGINAL ARTICLE

Jaideep Bhat · Jan Birch · Colin Whitehurst
Sean W Lanigan

A single-blinded randomised controlled study to determine the efficacy of Omnilux Revive facial treatment in skin rejuvenation

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Abstract To determine the efficacy of Omnilux Revive facial treatment in skin rejuvenation, twenty-three volunteers received randomised 20—Pámin treatments three times a week for three—Páweeks to one half of their face, with the untreated side acting as control. Regular assessments were carried out, focusing on parameters of subject satisfaction, photographic assessments, skin elasticity (Cutometer) and skin hydration (Corneometer CM825). Ninety-one percent of the volunteers reported visible changes to their skin. Blinded photographic evaluation reported a clinical response in 59% of the subjects. Objective analysis failed to show statistically significant changes in skin hydration or elasticity. The Omnilux Revive LED lamp is a safe alternative non-ablative skin rejuvenation treatment.

Keywords Facial skin rejuvenation · Omnilux Revive light emitting diode (LED) lamp

Introduction

The use of light technology in dermatology has grown rapidly over the last decade, with many developments in its use for the treatment of a wide variety of skin conditions from non-melanoma skin cancers [1] to facial resurfacing for photo-damaged skin [2–4].

Historically, the use of CO_2 lasers has been the mainstay of facial resurfacing and skin rejuvenation since the mid-1990s. It is accepted that photoageing and the subsequent visible effects of it are in part due to the breakdown of collagen by metalloproteinases and oxidative damage induced by exposure to UV light [5]. Subsequent treatment with CO_2 lasers improves these visible signs through tissue remodelling after cutaneous injury. However, the effectiveness of this technique is limited by prolonged healing times, discomfort during the procedure (requiring local anaesthesia) and the risk of complications such as pigmentary disorders [5]. This has led to a demand for new procedures that provide optimum results with minimal side effects.

LED technology has been at the forefront of new light source development in recent years. LED technology offers a new vehicle for the delivery of non-coherent light in arrays of varying shapes, suitable for the treatment of large surface areas.

Whelan et al have repeatedly proven the effectiveness of LED technology for delivering an optimum light dose, demonstrating the efficacy of LED therapy in tissue regeneration [6, 7].

The notion that the clinical manifestation of photodamage can be repaired by the application of selective wavelengths of light energy is a logical extension of the principles of non-selective ablation [5].

The various cell and tissue types in the body have their own unique light absorption characteristics, each absorbing light at specific wavelengths. Studies have demonstrated that selective wavelengths have stimulatory effects on cell types [8, 9]. Most importantly, this was demonstrated in the formation of precursors to collagen, procollagen and collagen type I as well as the enzymes associated with cellular structure [10–13].

This study combines this knowledge of LED technology with proven concepts of biostimulation to investigate whether this is a safe alternative to non-ablative skin rejuvenation. The objectives of the study were to establish whether light therapy using LEDs at a wavelength of 633—Pánm would stimulate facial skin rejuvenation. The hypothesis of the study was that Omnilux Revive facial treatment would rejuvenate the skin in nine treatments.

J. Bhat · S. W Lanigan (✉)
Lasercare Clinics Birmingham Skin Centre,
City Hospital NHS Trust, Dudley Road, Birmingham,
B18 7QH, UK
E-mail: sean.lanigan@swbh.nhs.uk
Tel.: +44-121-5076655
Fax: +44-121-5076649

J. Birch · C. Whitehurst
Photo Therapeutics Ltd, Station House, Stamford New Road,
Altrincham, WA14 1EP, UK

Materials and methods

Light source

Omnilux Revive (PhotoTherapeutics Ltd, Manchester, United Kingdom) is a LED-based light source, delivering non-coherent red light at a wavelength of 630(±3) nm and an intensity of 80—PámW/cm^2 at a dose of 96—PáJ/cm^2.

Clinical protocol

We enrolled 23 healthy volunteers, age range 31 to 56 (mean 44), with visible signs of ageing. For each healthy volunteer, age, sex, phototype and wrinkle grading were recorded. Phototype was evaluated using the Fitzpatrick classification (I—PôVI) [14]. Wrinkle grading was evaluated using an adapted version of the Glogau scale [10].

Volunteers had not received any previous aesthetic treatments to the treatment area within the previous six—Pámonths, including laser treatment and/or ablative or non-ablative cosmetic procedures. Volunteers were randomised in terms of receiving the light dose to either the right or the left side of the face. Control sides were occluded to prevent light incident on the skin. Subjects' faces were precleansed with Hidraderm cleansing lotion (SeS Derma, Valencia, Spain) and exposed to the light for 20—Pámin. Volunteers were treated three times weekly for three—Páweeks (nine treatments in total).

Measurements

Photography

Digital photographs were taken at baseline and at weeks three, eight and twelve using a Sony DSC-F707. Conditions for photography remained constant throughout the trial. Readings of skin elasticity and skin hydration were performed using a Cutometer (C & K Cutometers, Cardiff Biometrics, UK) and a Corneometer CM825 [11, 12] (CK Electronics, Köln, Germany). The skin measurements were performed at baseline and at weeks three, eight and twelve. Cutometer readings were taken from right and left temples and cheek areas of the subjects. Six corneometer readings were taken from the right and left cheek areas and analysed to determine changes in skin hydration.

Statistical analysis methods

A randomised control study of 23 patients allowed absolute differences in completed response rate of at least 40% to be detected at a 5% significance level using a two-sided multivariate test with 80% power, allowing 15% extra for dropouts.

Follow-up

During the study, volunteers were asked to qualitatively assess their response to the treatment. Volunteers were assessed using digital photography, clinical grading and elasticity and skin hydration measurements. All skin measurements were carried out at baseline and at weeks three, eight and twelve. Volunteer selection was random and the investigator was blind to it. Post-treatment photography was evaluated for treatment response at the end of the study by clinical investigators.

Results

Twenty-two volunteers completed the treatment course. Patient non-compliance led to a single drop-out.

Patient satisfaction

Eight weeks after the end of the study, 91% of the volunteers reported visible changes to their skin, indicating that even five—Páweeks after treatment, there was still a positive effect on the evaluation criteria (see Fig. 1). Sixty-four percent reported a reduction in fine lines and wrinkles and a perception of softer skin. Sixty-eight percent reported smoother skin, and over 50% reported that their skin felt firmer (Fig. 1). The therapy was well-tolerated and there were no reported side effects. No pain was encountered during the treatment regimen and there were no reported side effects such as erythema and swelling.

Elasticity and skin hydration

Statistical analysis demonstrated that the *P* values for elasticity and skin hydration were not statistically significant. It was noted that there was an initial drop in the

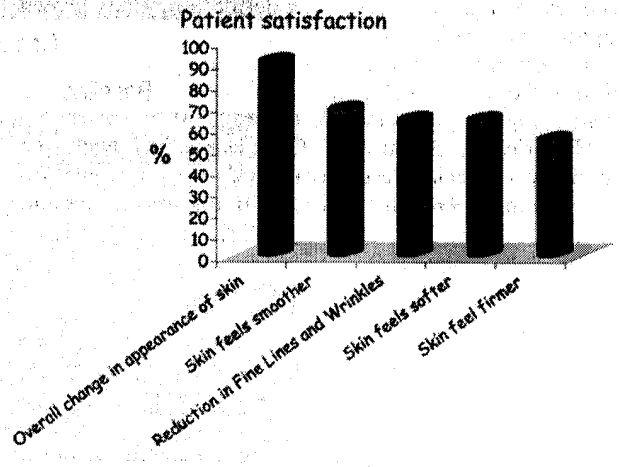


Fig. 1 Patient satisfaction from post-treatment assessment

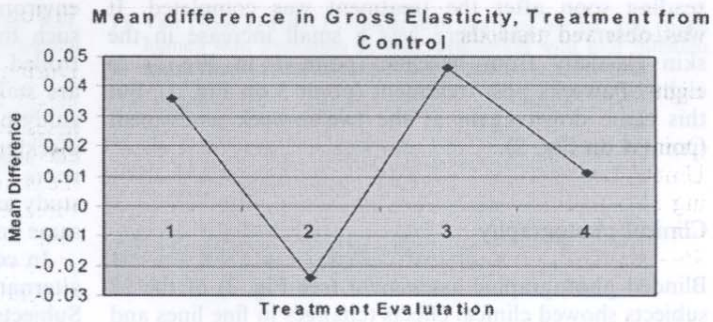
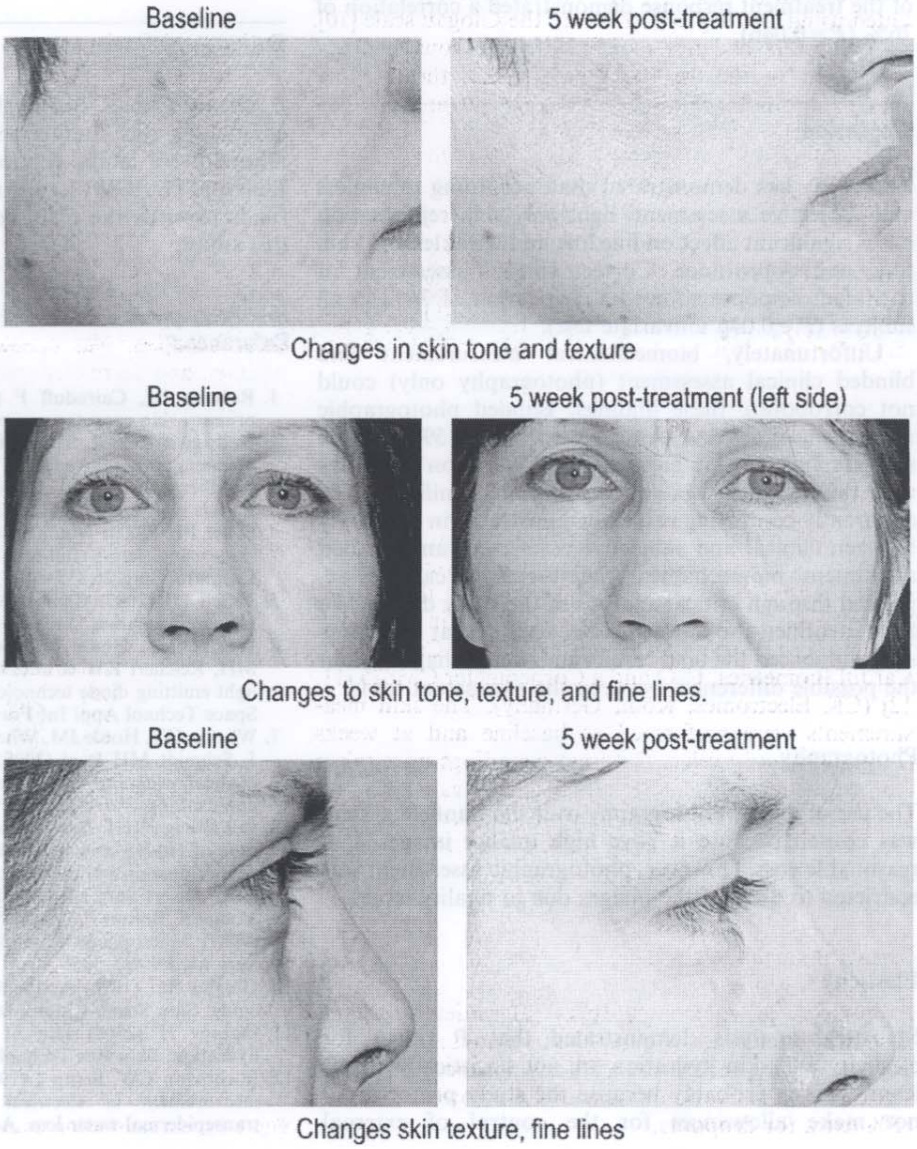


Fig. 2 Mean difference in gross eleasticity, treatment from control

mean difference in gross elasticity from baseline (point 1 in Fig. 2) in the initial four-week assessment (point 2 in Fig. 2) which thereafter increased to a maximal effect at eight-week assessment (point 3 in Fig. 2) and dropped thereafter to the baseline at twelve-week assessment (point 4 in Fig. 2). Point 1 in Fig. 2 was the baseline

Fig. 3 Changes in skin tone and texture



reading soon after the treatment was completed. It was observed that there was a small increase in the skin elasticity from baseline (point 1 in Fig. 2) to eight—Páweeks post-treatment (point 3 on Fig. 2), but this came down again at the twelve-week assessment (point 4 on Fig. 2).

Clinical photography

Blinded photographic assessment (see Fig. 3) of the 22 subjects showed clinical effects (changes in fine lines and wrinkles, skin tone and appearance) in 13 subjects (59%). Sets of colour prints were examined by two blinded observers together. However, the blinded clinical assessment by the investigator showed poor correlation for correct identification of treatment response with the treated side. Correct photographic assessment of the treatment response demonstrated a correlation of 76% ($P = 0.046$).

Discussion

This study has demonstrated that, according to clinical and subjective assessment, light-only skin rejuvenation has a significant effect on fine line and wrinkles and skin tone and appearance. Correct clinical assessment of treatment response showed a correlation of 76% in all subjects ($P = 0.046$ univariate test).

Unfortunately, biomechanical measurement and blinded clinical assessment (photography only) could not corroborate these findings. Blinded photographic assessment showed a clinical response in 59% of the subjects and the skin elasticity and hydration responses after the treatment were not statistically significant. The apparently conflicting results demonstrated in this study between clinical and subjective assessment and blinded assessment biomechanical measurements can be explained through critical analysis of the study design. We have identified the following key factors that have possibly influenced the final results and that perhaps explain the possible differences between the assessment tools.

Photography

The use of digital photography over the Canfield system was chosen because it gave high quality images at a reasonable cost. However, photographic assessment was restricted to 88% of the images due to quality issues.

Elasticity

Statistical analysis demonstrated that P values for elasticity and skin hydration are not statistically significant. This is probably because the study protocol did not make allowances for the control of external environmental conditions in the assessment room. All such measurements require the use of a climate-controlled room where temperature and relative humidity are stable throughout the study [15]. Importantly, the study protocol did not make allowances for the control of external environmental conditions in the assessment room. However, this was a within-patient controlled study and all paired measurements took place under the same environmental conditions.

In conclusion, Omnilux Revive LED lamp is a safe, alternative non-ablative skin rejuvenation treatment. Subjects found the treatment relaxing and therapeutic. Ninety-one percent of the subjects had a perception of treatment response (facial skin rejuvenation). Blinded photographic assessment reported a clinical response in 59% of subjects. Further research is required in this exciting area to correctly quantify the benefit obtained by this non-ablative facial skin rejuvenation treatment.

Disclosures

Lasercare Clinics, Birmingham, have received funds for conducting this study from the manufacturers of Omnilux Revive lamps (Photo Therapeutics, UK). Dr. J. Bhat and Dr. S. W. Lanigan have, however, not received funds towards the plan, conduction or presentation of this study.

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